Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2017/030

Scientific title of trial: An investigator initiated and conducted, multicentre, international, double-blinded, placebo-controlled, parallel-group, randomised controlled trial to determine the effect of more intensive blood pressure control provided by a fixed lowdose combination blood pressure lowering pill ("Triple Pill") strategy on top of standard of care, on time to first occurrence of recurrent stroke in patients with a history of acute stroke due to intracerebral hemorrhage

Date of commencement (enrolment of first participant): The first subject was randomized on 17 Oct 2017 at site 94024 - Kurunegala Teaching Hospital

Progression: 6 months

1 year

2 years

3 years

4 years

5 years X

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes. Protocol amendment version 5.0 dated 07 Sep 2021

Any changes to trial outcomes after commencement: None

2. Current status

Recruitment status: recruiting

Number assessed for eligibility: 952

Number recruited and allocated/randomized: 684

Number allocated/randomized to each intervention/arm (please edit as relevant): Data not available for each arm as study is double blind. The randomization ratio will be 1:1 Triple Pill vs. Placebo 1:1

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant): Data not available for each arm as study is double blind. Total number of losses-45 (After randomization) Total death -28, Lost to follow-up -1, Consent withdrawals - 16

Arm 1:

Arm 2:

3. Trial output

Date of trial completion ("last p	patient, last visit"): 30 June 2024
Final sample size: 1500	
Summary of Interim/Final data	a (if available):
N/A	
Abstract presentations of resul Note: please include a URL link Title of Abstract	Full citation (please include authors, date,
Note: please include a URL link	Full citation (please include authors, date, title of conference and place of presentation,
Note: please include a URL link	Full citation (please include authors, date,
Note: please include a URL link Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation,

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
None	

Name and signature of Responsible Registrant/ Principal Investigator

Date: 21 Oct 2022